

**REMARKS**

The present invention relates to a stent comprising a basic structure made of a material selected from the group consisting of a biodegradable plastic material and degradable metal, and a biodegradable shape memory polymer (SMP) material, which covers the basic structure, to systems including such stents, and to methods of manufacturing and implanting such stents.

In the Office Action dated February 4, 2010, claims 1 and 3-14 were rejected, with claims 1 and 3-11 being newly rejected under 35 U.S.C. § 103(a) based on US 2003/0153971 (Chandrasekaran) in view of US Patent 6,287,332 (Bolz et al), and claims 12-14 being rejected under 35 U.S.C. § 103(a) based on Chandrasekaran in view of Bolz et al, further in view of the previously cited Igaki reference. The Examiner also appears to rely up on U.S. Patent 6,160,084 (Langer et al), cited and incorporated-by-reference in Chandrasekaran at paragraph [0063]; in view thereof, it is respectfully submitted that the Examiner should also cite Langer et al on Form PTO-892 on the next Action issued.

In this Amendment, Applicant has added new independent claims 15 and 16, directed to further preferred embodiments. Support is found, e.g., at page 9, lines 4-5 and 19-23, and in the original claims, including, e.g., claims 3, 9, and 10. No additional fee is due.

Applicant respectfully traverses the §103 rejections, and submits that upon close consideration of the teachings of the Chandrasekaran and Bolz et al references as set forth below, it

will be seen that the present claims are not obvious in view thereof, and that the rejections should be withdrawn.

Chandrasekaran discloses a stent comprising a basic structure made of a metal (pars. [0030] and [0038]) which is covered with a biodegradable polymer, which can be an SMP as disclosed in Langer et al, US Patent 6,160,084 (par. [0063]). Chandrasekaran fails to disclose a stent comprising a the basic structure of a degradable metal, and further fails to disclose the alternative embodiment of a stent comprising a basic structure of a biodegradable polymer.

Bolz et al disclose stents formed of a degradable metal or metal alloy (see, e.g., col. 2, lines 6-16 and 26-34; and col. 3, lines 11-17).

In the first full paragraph at page 3 of the Office Action, it was asserted that it would have been obvious for a person of ordinary skill to substitute a degradable alloy (from Bolz et al) for the high density metallic reinforcing component taught by Chandrasekaran viz.,

“the metal reinforcing component therein can be constructed of a material having a high density, for example, platinum, tantalum, or gold...” (para. [0037])

but no reason/motivation for changing away from Chandrasekaran’s actual teaching is set forth (except hindsight reasoning). Therefore, Applicant respectfully submits that there is no reasonable motivation to encourage a person of ordinary skill in the art to depart from the teachings of paragraph [0037] of Chandrasekaran. Applicant additionally notes that in paragraph [0034], and particularly in the last two sentences thereof, Chandrasekaran emphasizes the importance of a non-degradable basic structure. For this reason the metallic reinforcement component of Chandrasekaran may be passivated to enhance “biostability” (par. [0035]). Therefore, a person following the

teaching of Chandrasekaran would not be motivated to make the drastic changes to Chandrasekaran that would be necessary to reach the presently claimed invention.

As to Chandrasekaran's incorporation of the SMPs disclosed in Langer et al, Applicant notes that in addition to the replacement of the polymers of Chandrasekaran, which generally do not show a shape memory effect, it would not be enough merely to select the SMPs of Langer et al; the person would need to further select those SMPs from Langer et al which are covalent networks and covalent polymer interpenetrating networks in order to reach the presently claimed invention. Although Langer et al also discloses covalent networks ("thermoset polymers"), there is a clear teaching of preference for thermoplastic polymers ( $\neq$  covalent networks) due to their ease of molding (see col. 6, lines 18-20).

Applicant also notes that various additional features as recited in other claims, such as claims 3 and 10, and new claims 15 and 16, provide additional distinctions over the cited art reference.

In view of the foregoing, Applicant respectfully submits that the new references and rejections do not establish a case of *prima facie* obviousness under 35 U.S.C. § 103, and hence the rejections should be withdrawn.

In view of the above, reconsideration and allowance of pending claims 1 and 3-16 of this application are now believed to be in order, and such actions are hereby earnestly solicited.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C. telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

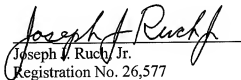
SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: June 4, 2010

  
Joseph V. Ruch Jr.  
Registration No. 26,577